MAR 1 1 2004 K033351

Confidential

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Global Orthopaedic Technology USA, Inc.
5349 Red Leaf Court
Oviedo, Florida 32765

Device: Global Resurfacing Unicompartmental Knee System

Classification Name: Knee Joint, Femorotibial, Metal/Polymer, Semi-constrained, Cemented Prosthesis (21 CFR 888.3530)

Intended Use: Partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. The device is a single-use implant intended for implantation with bone cement.

Device Description: The Global Resurfacing Unicompartmental Knee System consists of femoral and tibial components.

The femoral component is anatomic in design, to provide coverage of the condyle from posterior to anterior. The anatomic shape of the femoral component necessitates separate left and right geometries. A central keel and post on the back of the femoral component assists in cement fixation and rotational stability. The device is manufactured from cobalt chrome alloy that conforms to ASTM F-75-01.

The tibial component is semi-lunar in configuration and manufactured from compression molded ultra-high molecular weight polyethylene (UHMWPE) that conforms to ASTM F-648-00. The tibial component is universal in geometry.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disorders	Delayed wound healing	Hematoma
Fracture of bone cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive wear
Nerve damage		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2004

Mr. Carl Knobloch
Chief Operating Officer
Global Orthopaedic Technology, USA, Inc.
5349 Red Leaf Court
Oviedo, Florida 32765

Re: K033351
Trade/Device Name: Global Resurfacing Unicompartmental (GRU) Knee System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: February 16, 2004
Received: February 17, 2004

Dear Mr. Knobloch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033351

Device Name: Global Resurfacing Unicompartmental (GRU) Knee System

Indications For Use: The Global Resurfacing Unicompartmental (GRU) Knee System is intended for partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. The device is a single-use implant that is intended for use with bone cement.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033351